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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,538	08/17/2001	Steve J. D. Bell	37070/205236	5069

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,538	BELL ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 8-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 6-8-2004 are acknowledged. Claim 5 has been amended. Claims 1-11 are pending. Claims 1-4 and 8-11 remain withdrawn from consideration. Claims 5-7 are currently under examination.

Objections Withdrawn

The objection to claims 5-7 for being dependent on non-elected claims (inventions) is withdrawn in light of the amendment thereto.

The objection to the disclosure for failing to describe Figure 8 is withdrawn in light of the amendment thereto. It should be noted that the aforementioned objection might be reinstated after the resolution of the new matter rejection outlined below.

New Objections

The amendment filed 5-28-2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The deletion of Figure 8 constitutes new matter since it provides support for enablement of the instant claims. Moreover, it appears that the aforementioned deletion may have been made to avoid possible double patenting issues with copending applications

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 5-7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons of record.

Claim 5 is rendered vague and indefinite by the use of the phrase "induce immunity in a patient". It is still unclear what is meant by said phrase.

Applicant argues:

1. Said phrase, by its plain and simple meaning, means to induce an immunological response in a patient as demonstrated by page18, paragraphs 2 and 3).

Applicant's arguments have been fully considered and deemed non-persuasive.

It is still unclear what immunological responses are encompassed by said term. Applicant argues that said phrase refers to any immunological response while the phrase itself suggests that the term refers to the induction of protective immunity. Moreover, the portion of the specification cited by Applicant pertains to the use of calcium phosphate particles in vaccines (i.e. the induction of protective immunity).

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 5-7 under 35 U.S.C. 102(b) as being anticipated by Relyveld (U.S. Patent 4,016,252 – IDS- 4/15/02) is maintained for reason set forth in the previous Office action.

The instant claims are drawn methods of inducing immunity in a patient utilizing substantially smooth and substantially round calcium phosphate particles with a diameter ranging from 300 nm to 4000 nm coated and or impregnated with an antigen. Said particles are optionally used in compositions comprising said particles and a pharmaceutically acceptable carrier and other excipient wherein said particles are delivered to a mucosal surface.

Applicant argues:

1. Claim 5 has been amended to include the limitation that the particle "has a substantially spherical shape and a substantially smooth surface". Relyveld does not disclose said limitation.

2. There is not disclosure in Relyveld of the particles having a particular morphology, other than the statement that the gel exhibits "colloidal character".

3. The term "colloid" does not mean or infer a "substantially smooth" particle. Said substantially smooth particles are newly attainable through the process of the present invention.

4. The degree of control over the size and shape of the particles of the present invention and the ability to attain "substantially smooth" and "substantially spherical" particles results in greater control over the degree of antigenic material saturation which can be achieved in the particle.

5. Relyveld uses the term "colloidal character" to mean that the particles are so find that they remain suspended in a continuous medium, not to refer to their morphology.

6. The particles of the present invention may be even smaller than those disclosed by Relyveld.

7. Relyveld's rapid formation would change the size of the particles and cause them to be larger than the particles of the presently claimed invention.

8. The high molar concentration of its reactants will cause the gel of Relyveld to highly amorphous and resulting in particles that are larger than those of the presently claimed invention.

9. Relyveld does not contain the limitations that the antigenic material may coat the particle, may be impregnated in the particle or both.

10. The washing and purification steps described by Relyveld would result in the destruction of the antigenic materials coated on the particles as described in the present invention.

11. Although Relyveld discloses a calcium phosphate gel for use in adsorbing vaccines, it does not disclose that the gel is adapted to produce an immune response in a patient.

12. Adsorption of the vaccine teaches away from the instant invention that allows the antigenic materials to be readily released into the system thus producing an immune response.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Points 1-3 and 5, Relyveld disclose calcium phosphate particles with antigens adsorbed to them. Said calcium phosphate particles are deemed, in the absence of evidence to the contrary, to be the same as the calcium phosphate particles recited in the instant claims. Consequently, both the calcium phosphate compositions disclosed by Relyveld and those of the instant claims would have the same chemical, biological and **immunological** properties. This would include the ability to induce immunity. Moreover, although the reference does not disclose the calcium phosphate particles are "substantially smooth" and "substantially round", it is deemed, in absence of evidence to the contrary, that said characteristics are inherently possessed by calcium phosphate particles. Since the Office does not have the facilities for examining and comparing the product of the instant invention with the product disclosed in the prior art, the burden is on Applicant to show a novel or unobvious difference between the claimed product (calcium phosphate particles) and the product of the prior art. See In re Best 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The MPEP states:

A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best,* 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103

rejection is appropriate for these types of claims as well as for composition claims.

2112.01 Composition, Product, and Apparatus Claims
PRODUCT AND APPARATUS CLAIMS — WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT
Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada,* 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima *facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best,* 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).
COMPOSITION CLAIMS — IF THE COMPOSITION IS PHYSICALLY THE SAME, IT MUST HAVE THE SAME PROPERTIES
"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

With regard to Point 4, it seems that Applicant is arguing that the calcium phosphate particles of the instant invention are made novel and unobvious over those disclosed by Relyveld through the method of making said particles as disclosed in the specification. This argument would only be appropriate in Product-by-Process type claims. In Product-by-Process type claims, the process of producing the product is given no patentable weight since it does not impart novelty to a product when the product is taught by the prior art. See *In re Thorpe*, 227 USPQ 964 (CAFC 1985); *In re Marosi*, 218 USPQ 289, 292-293 (CAFC 1983) and *In re Brown*, 173 USPQ 685 (CCPA 1972). Consequently, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product *per se*, even when limited to the particular

process, is unpatentable over the same product taught in by the prior art. See *In re King*, 107 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); *In re Merz*, 97 F.2d 599, 601, 38 USPQ 143-145 (CCPA 1938); *In re Bergy*, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 US 902 (1978); and *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Finally, since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, **the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art**. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

With regard to Points 6-8, Applicant has made assertions but has failed to provide any factual evidence to support said assertions. Applicant is reminded that a statement or argument made by an attorney does not constitute factual evidence (see MPEP 716.01).

With regard to Point 9, Relyveld disclose that antigens are adsorbed to the calcium phosphate particles thereby meeting the limitation of the instant claims.

With regard to Points 10-11, Relyveld disclose "vaccine compositions" comprising calcium phosphate particles and antigen(s). To be considered a vaccine composition, the antigen would have to be capable of inducing a protective immune response in a patient.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., antigenic materials be readily released in into the system) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification,

limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

As outlined previously, Relyveld discloses an aqueous gel of calcium phosphate useful for the preparation of adsorbed vaccines, prepared by contacting an antigen with an aqueous gel and their use as vaccines (i.e. induce immunity). Relyveld discloses the use of an inactivated poliovirus as the "antigen" thereby targeting the resulting particles for mucosal (oral) delivery (see example 8). Moreover, Relyveld discloses the use of a sodium chloride solution as an excipient (see column3, lines 65-68). With regard to particle size, Relyveld discloses that his gel "exhibits a marked colloidal character". It is well known in the art that colloid is defined as a substance consisting of very tiny particles that are usually between 1 nm and 1000 nm in diameter and that are suspended in a continuous medium, such as a liquid, a solid or a gaseous substance. Therefore, Relyveld anticipates all the limitations of the claimed invention.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
August 16, 2004

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